DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

93769d

OCT 23 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Norman H. Kwan
President and CEO
Biomedical Implant Technology, Inc.
188 Bunting Road, Unit 8
St. Catharines, Ontario, CANADA

Dear. Dr. Kwan:

During an inspection of your facility located in St. Catharines, Ontario, Canada, on June 3-5, 2002, our investigator determined that your firm manufactures dental implant devices (endosseous implants) as well as other dental tools. The endosseous implants and other dental tools are medical devices as defined by Section 201(h) of the Federal, Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h).

The inspection revealed that your medical devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) Requirements set forth in FDA's Quality System Regulation (QSR), codified in the Code of Federal Regulations (C.F.R.), Part 820. The inspector noted the following violations:

1. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA), as required by 21 C.F.R. § 820.100(a). Your firm's procedure for implementing corrective and preventive actions (CAPA) does not include requirements for the following:

   a. Analyzing processes, work operations, complaints, returned product and other sources of quality data to identify existing and potential causes of nonconforming product;

   b. Investigating the cause of nonconformities relating to product, processes, and the quality system;

   c. Identifying the actions needed to correct and prevent recurrence of nonconforming product and other quality problems;

   d. Verifying or validating the CAPA to ensure that such action is effective and does not adversely affect the finished device;

e. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

f. Submitting relevant information on identified quality problems and CAPA for management review.

2. Failure to document your activities to analyze processes, quality reports, and quality records to identify existing and potential causes of nonconformities, as required by 21 C.F.R. § 820.100(a)(1) & (b).

3. Failure to document, as required by 21 C.F.R. § 820.100(a)(2) & (b), that you have investigated the causes of the following nonconformities relating to the one-piece dental implant: stuck guide pen; guide pin broke off; glass vials exploded; cracked and stained glass vials; glass vial inner diameters too small for the carriers; and rusted threads on the fixture device.

4. Failure to validate your processes with a high degree of assurance and to approve the processes according to established procedures, as required by 21 C.F.R. § 820.75. Specifically, the "[redacted]" has not been validated.

5. Failure to document the removal or reduction of a manufacturing material that could reasonably be expected to have an adverse effect on product quality, to ensure that the material is removed or limited to an amount that does not adversely affect the device's quality, as required by 21 C.F.R. § 820.70(h). Specifically, your firm failed to demonstrate that studies have been conducted to determine that the [redacted] mixture applied to the titanium device during the acid etching process is removed from the finished product.

6. Failure to establish and maintain a device history file (DHF) demonstrating that your one-piece dental implant device was developed in accordance with the approved design plan and the requirements of Part 820, as required by 21 C.F.R. § 820.30.

7. Failure to establish and maintain an adequate organizational structure to ensure that your medical devices are designed and produced in accordance with the requirements of Part 820, as required by 21 C.F.R. § 820.20(b). Specifically, at the time of the inspection your firm did not have a management representative appointed.

8. Failure to establish a management review procedure to ensure that the quality system satisfies the requirements of Part 820 and an established quality policy and objectives, and to document the dates and results of quality system reviews, as required by 21 C.F.R. § 820.20(c).

9. Failure to establish and maintain procedures for acceptance activities, as required by 21 C.F.R. § 820.80(a).

10. Failure to establish and maintain procedures for finished device acceptance for your one-piece dental implant, as required by 21 C.F.R. § 820.80(d).

11. Failure to establish and maintain procedures for acceptance of incoming product, as required by 21 C.F.R. § 820.80(b). Your firm has no procedure to ensure that all purchased or received product conforms to specified requirements in that:

    a. Your firm has not defined the type and extent of control to be exercised over the product, suppliers, and contractors based on evaluation results; and

    b. Your firm has not established and maintained records of acceptable suppliers and contractors.

12. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 C.F.R. § 820.198(a). The SOP for your complaint files only pertains to reports of actual or potential deaths or serious injuries.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure compliance with each requirement of the Act and FDA implementing regulations. The specific violations noted in this letter and in the FDA Form 483 issued at the end of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Given the serious nature of these violations of the Act, medical devices manufactured by your firm may be detained without physical examination upon presentation at a United States port of entry until these violations are corrected. In addition, United States federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within 15 days of receipt of this letter of the specific steps you have taken to correct the noted violations. Please explain each step you are taking identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur. Please include in your response any documentation necessary to show your plans for correction. An English translation of any foreign language materials should also be included in your response. Your response should be sent to the attention of Mr. Ronald L. Swann, Chief, Dental, ENT, and Ophthalmic Devices Branch, at the above letterhead address.

Sincerely yours,

Philip J. Frappaolo
Acting Director
Office of Compliance
Center for Devices and
Radiological Health